

## **REMARKS**

Claims 1-88 and 90-113 are pending. Claims 26-87 are withdrawn from consideration. Claims 1-25, 88, and 90-113 are under examination. In the present amendment, Applicant has amended claims 1 and 88 to recite "macerating whole tissue, wherein the whole tissue is not a microorganism, a virus, or blood." Those amendments are supported by the specification, for example, at page 14, lines 8-17; page 8, lines 20 and 22; and page 16, lines 12-13. Applicant has also amended claim 1 to recite "wherein the cationic surfactant accelerates maceration of the whole tissue by the at least one protease." That amendment is supported in the specification, for example, at page 16, lines 12-16.

Applicant has amended claim 23 to recite "at least one deoxyribonuclease inhibitor." That amendment is supported, for example, by claim 24. Applicant has amended claim 111 to recite "at least one deoxyribonuclease inhibitor." That amendment is supported, for example, by claim 112. Applicant has amended claim 17 to recite "at least one ribonuclease inhibitor." That amendment is supported, for example, by claim 18. Applicant has amended claim 105 to recite "at least one ribonuclease inhibitor." That amendment is supported, for example, by claim 106. Those amendments do not narrow the scope of the claims.

No new matter is added by the foregoing amendments.

Applicant also respectfully requests that the Examiner initial and return the Form PTO 1449, which was submitted in an Information Disclosure Statement filed November 21, 2001, to indicate that the listed documents have been considered.

**I. Rejection of claims 18, 19, 24, 25, 106, 107, 112, and 113 under 35 U.S.C. § 112, second paragraph**

The Examiner rejected claims 18, 19, 24, 25, 106, 107, 112, and 113 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Office Action at page 2, item 4.

The Examiner stated that there is insufficient antecedent basis for the phrase “wherein the at least one deoxyribonuclease inhibitor” in claims 24 and 112. Office Action at page 3, item 4. Claim 23 has been amended to recite “at least one deoxyribonuclease inhibitor,” thus providing antecedent basis for that phrase in claims 24 and 25. Claim 111 has been amended to recite “at least one deoxyribonuclease inhibitor,” thus providing antecedent basis for this phrase in claims 112 and 113.

The Examiner stated that there is insufficient antecedent basis for the phrase “wherein the at least one ribonuclease inhibitor” in claims 18, 106 and 107. Office Action at page 3, item 4. Claim 17 has been amended to recite “at least one ribonuclease inhibitor,” thus providing antecedent basis for that phrase in claims 18 and 19. Claim 105 has been amended to recite “at least one ribonuclease inhibitor,” thus providing antecedent basis for this phrase in claims 106 and 107.

Claims 18, 19, 24, 25, 106, 107, 112, and 113 are clear and definite. Withdrawal of the rejection of those claims under 35 U.S.C. § 112, second paragraph, is respectfully requested.

**II. Rejection of claims 1, 9-13, 15-17, 23-25, 88, 97-101, 103, 104, and 111-113 under 35 U.S.C. § 102(b)**

The Examiner rejected claims 1, 9-13, 15-17, 23-25, 88, 97-101, 103, 104, and 111-113 as allegedly being anticipated under 35 U.S.C. § 102(b) by Hewitt (U.S. Patent No. 4,900,677). Office Action at page 3, item 6.

The Examiner alleges that Hewitt “discloses [a] method of isolating nucleic acids, particularly DNA, from their source organism. By source organism is meant any organism which contains a nucleic acid, including cells, particularly microbial cells, viruses, and mycoplasma.” Office Action at page 3, item 6.

Without acquiescing to the rejection and solely to expedite prosecution, Applicant has amended claims 1 and 88 to recite “macerating whole tissue, wherein the whole tissue is not a microorganism, a virus, or blood” in the preamble. That phrase provides antecedent basis for the term “whole tissue,” which is recited in the body of claims 1 and 88. Applicant has also amended claim 1 to recite “wherein the cationic surfactant accelerates maceration of the whole tissue by the at least one protease.”

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP § 2131 at 2100-73 (8<sup>th</sup> ed. rev. 2, May 2004). Claim 1 recites a composition comprising “at least one cationic surfactant, at least one protease, . . . wherein the cationic surfactant accelerates maceration *of the whole tissue* by the at least one protease.” The specification defines the term “whole tissue” as including “ . . . any collection of cells organized to perform a specific function.” Specification at page 14, lines 8-9. Further, “whole tissue,” as recited in claim 1, is not “a microorganism, a virus, or blood.”

Hewitt does not discuss a composition comprising “at least one cationic surfactant, at least one protease, . . . wherein the cationic surfactant accelerates maceration *of the whole tissue* by the at least one protease.” The only sources of nucleic acid discussed by Hewitt are microbial organisms and cells in a buffered suspension. (See Hewitt, col. 5, lines 6-7, 25-30, 40-46, and 64-66.) Nowhere does

Hewitt discuss maceration of whole tissue. Thus, Hewitt does not expressly disclose each and every element of claim 1.

Further, Hewitt does not inherently disclose the composition of claim 1. Hewitt discusses a method using one or more “lytic enzymes” to release nucleic acids from a suspension of microorganisms. See Hewitt, col. 5, lines 62-64. The lytic enzymes discussed by Hewitt are highly specific for the unique cell wall and cell membrane components (e.g., certain peptidoglycans) of microorganisms. See Hewitt, col. 5, lines 64-68, and col. 6, lines 34-60 (discussing “bacteriolytic” enzymes). Such enzymes would not be expected to macerate whole tissue according to claim 1.

Although Hewitt also discusses using Proteinase K, which in certain embodiments of the present claims is effective in macerating whole tissue, any composition comprising Proteinase K that results from the method of Hewitt would not be expected to macerate whole tissue. Indeed, the only composition in Hewitt that comprises Proteinase K is a “lytic mixture,” which also comprises the viscous lysate of microorganisms already subjected to treatment by, *inter alia*, lytic enzymes and surfactant. See Hewitt, col. 7, lines 3-58. That composition would not be expected to macerate whole tissue according to claim 1. Thus, Hewitt cannot inherently anticipate claim 1.

Claim 88 recites a composition comprising “whole tissue, wherein the whole tissue is not a microorganism, a virus, or blood.” As discussed above, nowhere does Hewitt discuss a composition comprising “whole tissue.” Thus, Hewitt fails to disclose each and every element of claim 88.

Because Hewitt does not anticipate claim 1 or claim 88, Hewitt does not anticipate claims 9-13, 15-17, 23-25, 97-101, 103, 104, and 111-113, which ultimately depend from either claim 1 or claim 88. Because the Examiner has failed to establish anticipation for at least the reasons discussed above, Applicant need not address all of the Examiner's comments at pages 3-6, item 6, of the Office Action. By not addressing all of those comments, however, Applicant does not acquiesce to any of them.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 9-13, 15-17, 23-25, 88, 97-101, 103, 104, and 111-113 under 35 U.S.C. § 102(b).

**III. Rejection of claims 1, 3-6, 9-13, 15-17, 23-25, 88, 91-94, 97-101, 103-105, and 111-113 under 35 U.S.C. § 103(a)**

The Examiner rejected claims 1, 3-6, 9-13, 15-17, 23-25, 88, 91-94, 97-101, 103-105, and 111-113 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hewitt in view of Lienau et al. (U.S. Patent No. 6,548,256). Office Action at page 6, item 8.

The Examiner alleges that the "lysing and denaturing substance" of Lienau "includes a buffering agent, a salt, a detergent, and a protease. . . . The detergent is a quarternary amine cationic detergent, for example, cetyltrimethylammonium bromide (CTAB). . . . Therefore, it would have been obvious at the time the invention was made to use the surfactant of Lienau for the method of Hewitt." Office Action at pages 6-7, item 8.

To establish a *prima facie* case of obviousness, the cited documents must have taught or suggested all the claim elements. See MPEP § 2143 at 2100-129. As discussed above, Hewitt would not have taught or suggested a composition comprising "at least one cationic surfactant, at least one protease, . . . wherein the cationic

surfactant accelerates maceration of the whole tissue by the at least one protease,” as recited in claim 1. Further, Hewitt would not have taught or suggested a composition comprising “whole tissue, wherein the whole tissue is not a microorganism, virus, or blood,” as recited in claim 88.

Lienau would have failed to cure the deficiencies of Hewitt. Specifically, Lienau would have failed to teach or suggest “whole tissue.” Thus, the cited documents, either singly or in combination, would have failed to teach or suggest all the elements of claims 1 and 88.

The Examiner has failed to establish a *prima facie* case that claims 1 and 88 would have been obvious. Claims 3-6, 9-13, 15-17, 23-25, 91-94, 97-101, 103-105, and 111-113 ultimately depend from either claim 1 or claim 88. Thus, the Examiner has also failed to establish a *prima facie* case of obviousness with respect to those claims. Because the Examiner has failed to establish a *prima facie* case of obviousness for at least the reasons discussed above, Applicant need not address all of the Examiner's comments at pages 6-7, item 8, of the Office Action. By not addressing all of those comments, however, Applicant does not acquiesce to any of them.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1, 3-6, 9-13, 15-17, 23-25, 88, 91-94, 97-101, 103-105, and 111-113 under 35 U.S.C. § 103(a).

## **II. Objection to claims 2, 7, 8, 14, 20-22, 90, 95, 96, 102, and 108-110**

The Examiner objected to claims 2, 7, 8, 14, 20-22, 90, 95, 96, 102, and 108-110 “as being dependent upon a rejected base claim . . . .” Office Action at page 7, item 9. As discussed above, the base claims upon which the objected claims depend are in

condition for allowance. Thus, the Examiner's objection is moot. Applicant respectfully requests reconsideration and withdrawal of that objection.

### **CONCLUSION**

Applicant respectfully asserts that the application is in condition for allowance. If the Examiner does not consider the application to be in condition for allowance, Applicant requests that the Examiner call the undersigned at (650) 849-6778 to arrange an interview prior to taking action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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